

# **EXHIBIT 1**

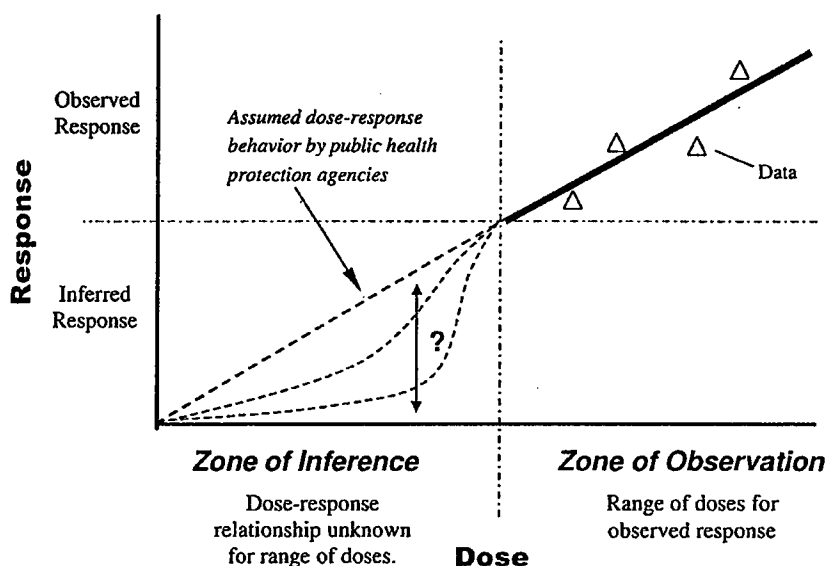
**Expert Report of Elizabeth Anderson, Ph.D.**

In re W.R. Grace & Co., *et al.*

October 3, 2006

or risk. In the figure the solid line represents the dose response relationship that is known, based upon data; the straight dashed line is the dose response assuming a linear non-threshold form through the origin and the two curved dashed lines are shown to represent an infinite series of possible dose response curves, any one of which could represent the actual relationship within the zone of inference.

**Figure 1. Zones of Inference and Observation**



The National Academy 1983 report *Risk Assessment in the Federal Government: Managing the Process* leaves no doubt that the health assessment process in the public health arena is composed of two components, the science-based component and the inference or policy-based component. As such, decisions that are required by statutes enacted by Congress to protect public health necessitate the use of policy-based assumptions in order to complete the assessment process and allow a regulatory decision to be made. These assessments are far different from science-based evaluations intended to establish causality.

Without actual evidence of low dose responses, the linear non-threshold model cannot be validated below the range of observed response. EPA acknowledges that the low dose response is uncertain and stated this clearly in its 1986 Cancer Risk Assessment Guidelines (EPA 1986b):

“It should be emphasized that the linearized multistage procedure [the most common no-threshold model] leads to a plausible upper limit to the risk that is consistent with some proposed mechanisms of carcinogenesis. Such an estimate, however, does not necessarily give a realistic prediction of the risk. The true value of the risk is unknown, and may be as low as zero.” (page 13)

Further, in the 2005 Guidelines for Carcinogen Risk Assessment, in the absence of mechanistic data that could be used to define the low-dose relationship, EPA recommends the following default position in assessing chemical carcinogenicity (EPA 2005):

“When the weight of evidence evaluation of all available data are insufficient to establish the mode of action for a tumor site and when [it is] scientifically plausible based on the available data, linear extrapolation is used as a default approach, because linear extrapolation generally is considered to be a health protective approach.” (page 3-21)

Others have supported this view. For example, Hodgson and Darnton (2000), in their review state, “The standard assumption is that, other things being equal, the risk will be proportional to dose; but this is more a cautious default assumption than anything more soundly based.” In fact, Hodgson and Darnton developed formulas for low-dose risk estimation that depart from the linear assumption and are more consistent with the low dose curves shown generically in Figure 1.

In his report in this matter, Dr. Suresh Moolgavkar has determined that the observed range for mesothelioma in epidemiological studies is associated with cohorts with mean exposure levels higher than about 15 f/ml-yr and that extrapolation is required to estimate risks associated with